

REMARKS/ARGUMENTS

In response to the enablement and indefiniteness rejections, applicant has amended the claim to note that the prevention aspect of the invention is practiced upon those having higher than normal risk of acquiring vaginal dryness, relative to the general female population. See the specification at page 13, lines 1-2. The art is well aware of age and other factors that puts a patient at elevated risk. Accordingly, it is urged that the scope of the claim, as amended, particularly points out and distinctly claims the subject matter applicant regards as the invention, and is enabled by the specification when read in light of the knowledge in the art. Accordingly, it is urged that both the enablement and indefiniteness rejections should be withdrawn.

Claim 1 stands rejected as allegedly obvious over Utsumi et al (U.S. Patent 4,005,200) in view of Blum et al (Gynecol. Obstet. Invest. 15: 10-15 (1983)) and Rodriguez (U.S. Patent 6,511,970). Applicant respectfully traverses this ground of rejection. Utsumi discusses the combination of DHEA with “estrogens” for treatment of “various” syndromes associated with climacterium - -with no indication that vaginal dryness is among the “various” syndromes contemplated by Utsumi. Even assuming *arguendo* that Utsumi intends to discuss vaginal dryness (and applicant does not believe that has been established for reasons set forth in Applicant’s prior response), Utsumi discusses combining DHEA with estrogen - - not selective estrogen receptor modulators (SERMs) as recited in the present claim.

As used in the present application, SERMs are a narrowly-defined class of compounds that function as estrogen receptor antagonists in breast tissue “yet [provide] estrogenic or estrogen-like effect on bone tissue and on serum cholesterol levels.” See the present specification at page 10, lines 5-8. It is likely that such compounds displaying antagonist properties in some tissues and agonist properties in other tissues were entirely unknown in 1975 when the application giving rise to the Utsumi patent was filed. It is urged that Utsumi, on its face, intended to define the term “estrogen” in its usual sense of estrogen receptor agonist. See Utsumi, column 2, lines 7-11 where Utsumi et al discuss conversion of DHA-S to natural “estrogens” by the placental tissue. Whatever unusual definition of “estrogen” Rodriguez may have used years

later should not be imputed to Utsumi et al, who appear to have had a more traditional definition in mind, i.e. natural estrogen agonists. It is axiomatic that a patentee may be his own lexicographer. And Rodriguez availed himself of that opportunity in the context of the Rodriguez patent the examiner cites. However, there is no reason to believe that Utsumi et al intended in 1975 to use the term "estrogen" to include the class of materials today known as SERMs. Accordingly, it is urged that the examiner's obviousness rejection should be withdrawn.

It is believed that the application is now in condition for allowance. Issuance of a notice of allowance is solicited.

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January 23, 2008

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Respectfully submitted,

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